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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,200	06/02/2006	Rasoul Sedaghat Kerdar	512100-2058	3356

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NEW YORK, NY 10151

EXAMINER
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LEA, CHRISTOPHER RAYMOND

ART UNIT	PAPER NUMBER
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1619

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12/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,200	<b>Applicant(s)</b> KERDAR ET AL.	
	<b>Examiner</b> Christopher R. Lea	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/02/2006</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

This application is a 371 (national stage application) of PCT/EP04/14148.

Claims 1-12 are pending. Claims 1-12 are under examination.

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

2. The information disclosure statement(s) (IDS) submitted on June 2, 2006, was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Any references not complying with 37 CFR 1.98 have been lined through and reason for non-compliance given on the form.
3. The information disclosure statement filed June 2, 2006, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. No copies of the foreign patent documents cited by applicants were found in the file wrapper; therefore, examiner is forced to conclude that, despite statements to the contrary, no copies were submitted.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "... and that it has a tear strength of at least 40 N", which is indefinite. It is unclear whether "it" is referring to the dosage form or the active ingredient-containing layer. It would be remedial to amend the claim by replacing "it" with the noun it represents. Since claims 2-9 ultimately depend from claim 1, they have been rejected under 35 U.S.C. 112 second paragraph as well.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

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USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 2** recites the broad recitation "at least 50 N", and the claim also recites "at least 60 N" which is the narrower statement of the range/limitation. Also In the present instance, claim 3 recites the broad recitation "cellulose ether", and the claim also recites "hydroxyethylcellulose, methylcellulose, hydroxypropylcellulose, and/or hydroxypropylmethylcellulose" which is the narrower statement of the range/limitation.

Regarding claims 2 & 3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

6. Claims 10-12 provide for the use of a lidocaine-containing layer in film form, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 10-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Examiner reserves the right to impose restriction requirement on the instant claims if applicants amend claims 10-12 in a manner that deems such a restriction proper.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupprecht et al. (US PreGrant Publication 2002/0142036).

### **Applicant claims**

Applicant claims a laminar film dosage form containing hydrophilic polymers and lidocaine.

### **Determination of the scope and content of the prior art (MPEP 2141.01)**

Rupprecht et al. teach, as a whole, active agent-containing multi-layer film of hydrophilic polymers.

Claims 1, 2, 6, & 7: Rupprecht et al. teach an active agent-containing multi-layer film of film-forming polymers with a cover layer, at least one active substance-containing layer, and an adherent layer (paragraph 2). Rupprecht et al. teach that the adherent layer is mucoadhesive and the multi-layer film is useful for transmucosal, which includes nasal, administration (paragraphs 47 & 48 and claim 15). Rupprecht et al. teach that the active ingredient consists of hydrophilic polymers crosslinked *in situ* (paragraph 8). Rupprecht et al. teach that lidocaine is among the possible active agents which may be incorporable into the multilayer film (paragraph 30). Rupprecht et al. teach the multi-layer film consists of up to 30% active substance based on the overall weight of the film (paragraph 46). This percentage overlaps with the claimed range of 30-60% when one considers that the claimed range is based only on the total weight of the crosslinked polymer, not the overall dosage form. As to the claimed tear strength, where the

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claimed and prior art products are substantially identical in composition, a *prima facie* case of either obviousness has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the claimed tear strength, since it is substantially identical to the claimed composition (See MPEP § 2112.01).

Claim 3: Rupprecht et al. teach cellulose ethers, particularly hydroxypropyl-methylcellulose as the hydrophilic polymers in the active substance-containing layer (paragraph 20).

Claim 4: Rupprecht et al. teach crosslinking the hydrophilic polymer *in situ* (paragraphs 8 & 9).

Claim 5: Rupprecht et al. teach adding additional polymers to control the release of the active substance (paragraphs 23 & 24).

Claim 8: Rupprecht et al. teach that the active agent diffuses through the adherent layer, so the adherent layer is active ingredient containing. (paragraph 10). Further, Rupprecht et al. teach that (mucoadhesive) polyacrylic acid polymer (which makes the adherent layer adherent) may be added to the active substance-containing



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layer, which would make allow an active substance-containing layer to be the adhesive layer (paragraph 23).

Claim 9: Rupprecht et al. teach that the covering layer acts as a barrier to prevent diffusion of (i.e., is impermeable to) the active agent (paragraph 10).

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

The difference between the teachings of Rupprecht et al. and the instant claims is that Rupprecht et al. do not specifically embody the use of lidocaine as the active agent.

**Finding of *prima facie* obviousness  
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to select lidocaine from the list of acceptable active agents and incorporate it into the dosage form taught by Rupprecht et al. and produce the instant invention. The skilled artisan would have been motivated to do this because the selection of a known substance based on its suitability for its intended use would have been obvious to the skilled artisan. Further it would have been obvious to select an active agent from the list based on its known abilities and functions. Maizels et al. (JAMA, 276(4), pages 319-321, cited by applicants) teach administering lidocaine nasally for the treatment of migraine headaches; therefore, it would have been obvious to incorporate lidocaine into a dosage form that can be administered nasally, especially one that could offer control of the release profile.

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In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in selecting lidocaine from the list of acceptable active agents incorporable into the dosage form of Rupprecht et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

Claims 1-12 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Mina Haghighatian/  
Primary Examiner, Art Unit 1616